

PROPOSED AMENDMENTS TO THE CLAIMS

Applicants respectfully request this Listing of Claims replace all prior versions and listings of the claims in this application:

Listing of Claims:

1.-95. (canceled)

96. (presently amended) A process for the preparation of a solid composition which is capable of being formed into a solid oral dosage form for delivery to an intestine comprising the step of:

a) providing a blend of a hydrophilic or macromolecular drug and, as an enhancer:

(i) a salt of a medium chain fatty acid having a carbon chain length of from 6 to 20 carbon atoms;

(ii) a medium chain fatty acid halide derivative, a medium chain fatty acid anhydride derivative, or a medium chain fatty acid glyceride derivative, each of said derivatives having a carbon chain length of from 6 to 20 carbon atoms; or

(iii) the fatty acid salt of clause (i) having, at the end opposite the fatty acid salt, an acid halide, an acid anhydride, or glyceride moiety;

(iv) an acid halide derivative of clause (ii) above having, at the end opposite of the halide portion, an acid halide, acid anhydride, or glyceride moiety;

(v) an anhydride derivative of clause (ii) above having, at the end opposite of the anhydride, an acid anhydride, acid halide, or glyceride moiety; or

(vi) a glyceride derivative of clause (ii) above having, at the end opposite of the glyceride portion, a glyceride, an acid halide, or acid anhydride moiety;

which blend also comprises, optionally, another constituent(s); wherein said blend and each of said drug, enhancer, and optional constituent(s) is a solid at room

temperature.

97. (previously presented) The process according to claim 96 wherein the drug and the enhancer are blended in a ratio of from 1:100,000 to 10:1 (drug: enhancer).

98-109.(canceled)

110. (new) The process according to claim 96, wherein the carbon chain length is from 8 to 14 carbon atoms.
111. (new) The process according to claim 96, wherein the enhancer is a sodium salt of a medium chain fatty acid.
112. (new) The process according to claim 111, wherein the enhancer is selected from the group consisting of sodium caprylate, sodium caprate and sodium laurate.
113. (new) The process according to claim 96, wherein the drug is a polysaccharide, an oligosaccharide, a protein, a peptide, or a bisphosphonate.
114. (new) The process according to claim 113, wherein the polysaccharide is low molecular weight heparin.
115. (new) The process according to claim 96, wherein the dosage form is a tablet, a capsule or a multiparticulate dosage form.
116. (new) The process according to claim 115, wherein the dosage form is a delayed release dosage form.
117. (new) The process according to claim 115, wherein the dosage form further comprises a rate-controlling polymer material.

118. (new) The process according to claim 117, wherein the rate-controlling polymer material is HPMC.
119. (new) The process according to claim 117, wherein the rate-controlling polymer material is a polymer derived from acrylic or methacrylic acid and their respective esters or copolymers derived from acrylic or methacrylic acid and their respective esters.
120. (new) The process according to claim 117 further comprising the steps of compressing the drug and enhancer and at least one auxiliary excipient into tablet form and coating said tablet form with the rate-controlling polymer material.
121. (new) The process according to claim 116 further comprising the steps of compressing the drug and enhancer and at least one auxiliary excipient into tablet form and coating said tablet form with a delayed release polymer.
122. (new) The process according to claim 117 further comprising the steps of compressing the drug and enhancer and at least one auxiliary excipient into the form of a multilayer tablet and coating said multilayer tablet with the rate-controlling polymer material.
123. (new) The process according to claim 116 further comprising the steps of compressing the drug and enhancer and at least one auxiliary excipient into the form of a multilayer tablet and coating said multilayer tablet with a delayed release polymer.
124. (new) The process according to claim 117 further comprising the steps of dispersing the drug and enhancer in the rate-controlling polymer material and compressing said rate-controlling polymer material into the form of a multilayer tablet.

125. (new) The process according to claim 124 further comprising the step of coating the multilayer tablet with a rate-controlling polymer material.
126. (new) The process according to claim 124 further comprising the step of coating the multilayer tablet with a delayed release polymer.
127. (new) The process according to claim 117 further comprising the step of combining the drug, the enhancer, at least one auxiliary excipient, and the rate-controlling polymer material into a multiparticulate form.
128. (new) The process according to claim 127, wherein the multiparticulate comprises discrete particles, pellets, minitabets, or combinations thereof.
129. (new) The process according to claim 128, wherein the multiparticulate comprises a blend of two or more populations of particles, pellets or mini-tablets having different in vitro or in vivo release characteristics.
130. (new) The process according to claim 127 further comprising the step of encapsulating the multiparticulate in a hard or soft gelatin capsule.
131. (new) The process according to claim 130 further comprising the step of coating the capsule with the rate-controlling polymer material.
132. (new) The process according to claim 130 further comprising the step of coating the capsule with a delayed release polymer material.
133. (new) The process according to claim 127 further comprising the step of incorporating the multiparticulate into a sachet.
134. (new) The process according to claim 128 further comprising the step of compressing the discrete particles or pellets into tablet form.

135. (new) The process according to claim 134 further comprising the step of coating the tablet with the rate-controlling polymer material.
136. (new) The process according to claim 134 further comprising the step of coating the tablet with a delayed release polymer material.
137. (new) The process according to claim 128 further comprising the step of compressing the discrete particles or pellets into a multilayer tablet.
138. (new) The process according to claim 137 further comprising the step of coating the multilayer tablet with the rate controlling polymer material.
139. (new) The process according to claim 137 further comprising the step of coating the multilayer tablet with a delayed release polymer material.
140. (new) A method of treatment of a medical condition comprising administering orally to a patient suffering from said medical condition a therapeutically effective amount of the solid composition prepared by the process of claim 96.
141. (new) The process according to claim 96 further comprising the step of directly compressing the blend to form said solid oral dosage form.
142. (new) The process according to claim 96 further comprising the step of granulating the blend to form a granulate for incorporation into said solid oral dosage form.
143. (new) The process according to claim 141 wherein the drug and the enhancer are blended in a ratio of from 1:100,000 to 10:1 (drug: enhancer).

144. (new) The process according to claim 142 wherein the drug and the enhancer are blended in a ratio of from 1:100,000 to 10:1 (drug: enhancer).
145. (new) A pharmaceutical composition made by the process of claim 96.
146. (new) The process according to claim 115, wherein the dosage form is a capsule.
147. (new) The process according to claim 146 further comprising the step of coating the capsule with a rate-controlling polymer material.
148. (new) The process according to claim 146 further comprising the step of coating the capsule with a delayed release polymer material.
149. (new) The process according to claim 96, wherein the enhancer is the only enhancer present in the dosage form.
150. (new) The process according to claim 149, wherein the enhancer is one or more members selected from the group consisting of a salt of a fatty acid having a carbon chain length of from 8 to 14 carbon atoms.
151. (new) The process according to claim 149, wherein the fatty acid salt is a sodium salt.
152. (new) The process according to claim 151, wherein the enhancer is selected from the group consisting of sodium caprylate, sodium caprate, and sodium laurate.
153. (new) The process according to claim 149, wherein the drug is a polysaccharide, an oligosaccharide, a protein, a peptide or a bisphosphonate.
154. (new) The process according to claim 153, wherein the polysaccharide is low molecular weight heparin.

155. (new) The process according to claim 149, wherein the drug and the enhancer are present in a weight ratio of from 1:100000 to 10:1 (drug: enhancer).
156. (new) The process according to claim 149, wherein the solid oral dosage form is selected from the group consisting of a tablet, a capsule, and a multiparticulate.
157. (new) The process according to claim 149 further comprising the step of forming the composition into a solid oral dosage form by direct compression.
158. (new) The process according to claim 149 further comprising the step of forming the composition into a solid oral dosage form by granulating the composition to form a granular material.